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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,588	08/22/2003	Brian P. Watschke	240993US25	9478
22850 7590 01/29/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER LUSTUSKY, SARA	
			ART UNIT	PAPER NUMBER
			3735	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/645,588

Applicant(s)

WATSCHKE ET AL.

Examiner

Sara Lustusky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-20 is/are allowed.
- 6) ☒ Claim(s) 1,3,8,9,11 and 12 is/are rejected.
- 7) ☒ Claim(s) 2 and 4-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2006 and 22 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/23/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The Examiner acknowledges the Amendment submitted by Applicant dated August 23, 2006. Amended claims 3-4, 7, 14-15 and 18-19 are acknowledged. Claim 10 has been cancelled. Claims 1-9 and 11-20 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 23, 2006 in response to the Office Action dated May 23, 2006 has been considered by the examiner.

Specification

The amendments to the specification have been considered. The objections to the specification set forth in the Office Action dated May 23, 2006 are withdrawn.

Drawings

The drawings regarding Figures 5 and 6 were received on August 23, 2006. These drawings are acceptable. However, not all of the required drawing amendments have been made as set forth in the drawing objections stated in the Office Action dated May 23, 2006.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because reference character "20" has been used to designate both the vagina and the lower sheath. While Applicant has stated in the Amendment dated August 23, 2006 that reference character 20 indicates the lower sheath and reference character 200 indicates the vagina, these two reference characters point to identical locations in Figures 6-7 and 9-10. Furthermore, in Figure 7 the lower sheath structure is clearly visible but reference character 20 distinctly indicates the vagina. Corrected drawings are required in reply to the Office action to

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avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8: It is unclear what is meant by the recitation "the central portion of the sling is free of any overlapping sheath portions" in line 5. It has been disclosed in claim 1 that each upper sheath envelops an upper portion of the sling and that the lower sheath envelopes the central portion of the sling. It is unclear how the central portion of the sling is free of overlapping sheath portions if the upper sheaths and lower sheath have overlapping portions as recited in claim 8 if the sling is enveloped by this sheath configuration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 7-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al. (US 2004/0039246 A1) in view of Gellman et al. (US 2002/0156488 A1).

Claim 1: Gellman et al. (US 2004/0039246 A1) teaches a sling assembly, comprising:

- a. A surgical sling (2) configured to be implanted during a surgical sling procedure, and including first (14) and second regions (24) and a central portion (logically between the first and second regions);
- b. A removable sheath assembly situated about the surgical sling (as seen in Figure 11a), the removable sheath assembly comprising; first and second upper sheaths (the examiner interprets this limitation to include sheaths that cover a sling on the right and/or left portions), described in line 2 of paragraph [0046], a lower sheath (310) (as seen in Figure 11a), the lower sheath (310) configured to be situated about the central portion of the surgical sling, as described in line 2 of paragraph [0037], (as seen in Figure 11a) and to be in cooperative association with both the first and second upper sheaths, described in lines 1-5 of paragraph [0046].

Claim 3: Gellman et al. (US 2004/0039246 A1) teaches the sling assembly of claim 1, wherein the lower sheath (310) defines an interior portion that envelopes the surgical sling (300) and an exterior portion which has first and second faces (as seen in Figures 11a-11b), the first face configured to be placed adjacent to a patient's urethra, described in line 2 of paragraph [0039] (as seen in Figures 9a-9c), and the first face includes a score places longitudinally along its length (as seen in Figure 11b).

Claim 7: Gellman et al. (US 2004/0039246 A1) teaches all of the claim limitations of claim 1, as described above, wherein the sling assembly further comprises a dilator for creating or expanding a tissue passageway for placement of said sling (as described in paragraph [0143]).

Claim 12: Gellman et al. (US 2004/0039246 A1) teaches that the sling in the sling assembly of claim 1 is elastic, as described in lines 1-7 of paragraph [0086].

While Gellman et al. ('246) teaches that the sheath described in paragraph [0046] is a protective sheath, Gellman et al. ('246) does not teach the specific structural configuration of said sheath or the type of sheath, nor does it teach the use of a spacer.

Gellman et al. ('488) teaches a protective sheath for encasing a sling, wherein said protective sheath is perforated (at 60) (as seen in Figures 3a-b and 5F-6) (as described in paragraph [0149]) in order to increase the ease of removal by reducing the friction against the tissue that often occurs when removing the entire length of a sleeve through the same location, and to increase the number of locations by which said protective sheath may be removed.

Gellman et al. ('488) further teaches the use of a spacer (100) configured to be placed between the surgical sling (10) and the patient's urethra (999) (as seen in Figures 5A, 5E, 5F), described in lines 13-15 of paragraph [0160].

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a perforated protective sheath similar to that of Gellman et al. ('488) as the protective sheath in a sling assembly similar to that of Gellman et al. ('246) in order to reduce the risk of injury to the surrounding tissue during removal of the protective sheath by removal through one a single location.

It would have been further obvious to one of ordinary skill in the art to use the spacer of Gellman et al. ('488) with the sling assembly of Gellman et al. ('246) because a spacer is helpful in adjusting the tension and position of the sling during its placement, described in lines 6 and 23 of paragraph [0160] of Gellman et al. ('488). The amount of tension a sling puts on the surrounding tissue is important with respect to the assembly's effectiveness after implantation.

Allowable Subject Matter

As set forth in the Office action dated May 23, 2006 and in view of the statements above, claims 2 and 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 2, none of the prior art of record teaches or fairly suggests a sling assembly having a first and second upper sheath and a partially overlapping central sheath with a first face including a kiss cut.

Regarding claim 4, none of the prior art of record teaches or fairly suggests a sling assembly comprising first and second upper sheaths and a partially overlapping lower sheath, the lower sheath having a tab portion on one face.

Regarding claims 5-6, none of the prior art of record teaches or fairly suggests a sling assembly comprising first and second upper sheaths and a partially overlapping lower sheath having a removal assembly operatively associated with the lower sheath.

Claims 13-20 are allowed over the prior art of record.

Regarding claims 13-20, none of the prior art of record teaches or fairly suggests a method for implanting a sling comprising the steps of providing a sheath assembly including two upper sheaths and a lower sheath wherein the lower sheath is removed via at least one vaginal incision and the upper sheaths are removed via at least one suprapubic incision.

Response to Arguments

Applicant's arguments on page 13 of the Amendment dated August 23, 2006 regarding the rejection of claims 8 and 9 under 35 U.S.C. 112, second paragraph, have been fully considered but they are not persuasive.

The Examiner thanks Applicant for the clear explanation of claims 8 and 9, wherein Applicant has stated that the first, second and lower sheath have a telescoping relationship, wherein the lower sheath has first and second overlapping regions at ends proximate to both said first and second upper sheaths without having overlapping portions at the central portion. While the Examiner found Applicant's explanation to be helpful, the claim language does not reflect Applicant's explanation. The limitations in claim 1 teach that the lower sheath is situated about the central portion of the sling. The language of claim 8 states that the lower sheath and the first upper sheath overlap at one end and that the lower sheath and the second upper sheath overlap at the opposite end. The recitation "so that the central portion of the sling is free of any overlapping sheath portions" does not expressly teach that it is the *first* and *second upper sheaths* that do not overlap *each other* at the central portion of the sling. The limitation "central portion" does not expressly teach how much of the sling is considered to be part of the portion. In view of the claim language of claim 1, the entire length of the lower sheath could be considered to be the central portion of the sling. Therefore the first and second overlapping portions of sheaths (first, second and lower) occur at the central portion of the sling.

Applicant's arguments filed August 23, 2006 on page 14 regarding the rejection of claims 1, 3 and 12 under 35 U.S.C. 102(e) in view of Gellman et al. (2004/0039246 A1) have been fully

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considered but they are moot in view of the new ground(s) of rejection. However, the Examiner offers the following explanation.

Applicant has stated that the non-synthetic sheath of Gellman et al. ('246) is not a removable sheath with first and second upper sheaths and that said non-synthetic sheath is attached to the sling.

Gellman et al. ('246) clearly states that the protective sleeve (i.e. sheath) may fully or partly encase the sling and may be used in combination with any of the embodiments of the invention, as described in paragraph [0046], and that the sleeve may be removed according to various methods once the sling has been implanted. When used in the embodiment seen in Figure 11a, the protective sleeve or sheath cooperatively associates with the sling and non-synthetic material sheath. Because neither the specification nor the claims define the meaning of cooperatively associate, the Examiner considers the protective sheath and the non-synthetic sheath to be in cooperative association as they are each strategically positioned over the sling and with respect to each other such that they may overlap if desired according to the description set forth in paragraph [0046]. In this arrangement, the non-synthetic material comprises the lower sheath of Applicant's invention as it sheaths the central portion of the sling, as seen in Figures 11a-b. In the embodiment seen in Figures 11a-b, the non-synthetic sheath is not attached to the sling, as described in paragraph [0170], but is merely crimped to prevent it from unintentionally falling off of the sling, as seen in Figure 11b, and therefore may be removed. Regarding embodiments where the non-synthetic sheath is attached to the sling, attachment options disclosed include sutures, staples and clips (as described in paragraph [0037]), which are commonly used in the art as temporary stabilizers and may be easily removed if desired.

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Applicant argues that the sheath assembly of Gellman et al. ('246) would not allow the removability of the present invention. As described above, Gellman et al. ('246) teaches all the structural limitations of claims 1, 3 and 12 and therefore is capable of performing the intended use.

Applicant's arguments filed August 23, 2006 on page 15 regarding the rejection of claim 11 under 35 U.S.C. 103(a) in view of Gellman et al. (2004/0039246 A1) and Gellman et al. (2002/0156488 A1) set forth in the Office Action dated May 23, 2006 have been fully considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chu et al. (US 2004/0116944 A1) teaches various configurations of a sling and a sheath assembly. Scetbon (US 2001/0018549 A1) teaches a perforated sleeve and sheath assembly.

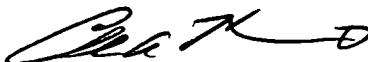
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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